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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,278	03/16/2001	Sumio Kawano	KNI-148-A	7912
21828	7590	10/24/2005	EXAMINER	
CARRIER BLACKMAN AND ASSOCIATES			TANINGCO, MARCUS H	
24101 NOVI ROAD			ART UNIT	
SUITE 100			PAPER NUMBER	
NOVI, MI 48375			2884	

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,278

Applicant(s)

KAWANO ET AL.

Examiner

Marcus H. Taningco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soller et al. (US 6,006,119) in view of Wright et al. (US 6,483,583).

Re claim 1, Soller discloses an analytical method of analyzing blood using near infrared spectroscopy comprising the steps of applying light through a blood collection receptacle having a wavelength of 700nm- 1100nm (Col. 11, 51-55) to a sample of the blood contained in the receptacle (Col. 2, 8-12). Soller further discloses detecting at least one of diffusely reflected light, diffusely transmitted light, and diffusely transmitted and reflected light from the blood sample in the blood collection receptacle by an optical sensor to measure a near infrared absorption spectrum of the blood sample (Col. 2, 31-44). Soller further discloses modifying the measured spectrum using a calibration equation, which has been determined in advance (Col. 6, 58-67; 41-50), from a spectrum measured using a receptacle with the same specifications as the said blood collection receptacle and following the steps above relative to blood specimen with known object characteristics, thereby determining an object characteristic of the blood sample (Col. 10, 18-38). Soller discloses the claimed invention, but fails to teach light applied to a

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ceramic plate so as to obtain an intensity of the light transmitted through the ceramic plate as a reference value for measurements of said optical sensor involving said blood collection receptacle and said receptacle with the same specifications as the said blood collection receptacle. Wright teaches that it is known to use a ceramic tile as a reference material to calibrate the spectrometer (Col. 2, 40-53). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method taught by Soller to include the ceramic tile in order to correct for instrument response variation and provide a reference value for measurements as suggested by Wright.

Re claim 3, Soller discloses a method for analyzing oil using near infrared spectroscopy (Col. 1, 25-34).

Re claim 4, Soller discloses a method wherein the sample is collected into test tubes (Col. 1, 18-21) of the recited type (Col. 5, 53-64).

Re claim 14, Soller discloses a method wherein the sample is collected into test tubes (Col. 1, 18-21) of the recited type (Col. 5, 53-64).

Re claim 15, Soller discloses an analytical apparatus for analyzing blood wherein the calibration equation is determined in advance using the near infrared apparatus in relation to a plurality of blood specimens with different, known object characteristics (Col. 10, 18-38).

Re claim 16, Soller discloses a method for analyzing a blood sample using NIR (Col. 3, 6-13).

Claims 5, 6, 8-14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soller et al. and Wright et al. in view of Brown et al. (US 4,134,678).

Re claim 5, Soller discloses an analytical apparatus for analyzing blood comprising a block provided with: a housing portion for a blood collection receptacle (Col. 20, 6); a near infrared apparatus provided with a spectroscope for dispersing near infrared light from a light source having a wavelength of 700nm-1100nm (Col. 11, 51-55) or from a sample of blood contained in the blood collection receptacle and an optical sensor for detecting the near infrared light (Col. 2, 31-44); a light conduction means for conducting the near infrared light emitted from the light source or the spectroscope to the blood collection receptacle within the housing portion and for conducting, directly or through the spectroscope, at least one of diffusely reflected light, diffusely transmitted light, and diffusely transmitted and reflected light from the blood sample within the blood collection receptacle to the optical sensor (Col. 19, 34-44); and a control means for outputting a measured spectrum of the blood sample to the near infrared apparatus and for modifying the measured spectrum using a calibration equation that has been determined in advance (Col. 6, 58-67; 41-50) from a spectrum measured using the apparatus, a receptacle with the same specifications as the said blood collection receptacle and blood specimens with known object characteristics, for thereby computing an object characteristic of the blood sample (Col; 19 and 20, 42-55 and 10-17, respectively). It is obvious that the calibration equation determined in advance would be determined using a receptacle with the same specifications as the blood collection receptacle used to determine the object characteristics of the sample being analyzed in order to insure standardization and consistency in measurement results of the unknown sample.

Re claim 6, Soller discloses an analytical apparatus for analyzing blood wherein a white light source (Col. 19, 40-41) is used as the light source, and a diode array (Col. 19, 43) is used as

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the optical sensor. It is obvious and well known in the art that a tungsten lamp is a white light source, therefore it is the position of the Office that the reference of Soller reads upon the applicants' claimed limitation.

Re claim 8, Soller discloses an analytical apparatus for analyzing blood wherein the light conduction means comprises an optical fiber (Col. 12, 59-62).

Re claim 9, Soller discloses the claimed invention but fails to show a block provided with a temperature control means for stabilizing the blood sample within the blood collection receptacle at a predetermined temperature. Brown shows that it is known to provide a temperature regulator (Col. 8, 16-25) for a automatic blood analysis apparatus. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the apparatus of Soller in view of Benz and Brown with the temperature regulator of Brown for the purposes of providing a means for regulating the temperature of a sample being analyzed.

Re claim 10, Soller discloses an analytical apparatus for analyzing blood wherein the blood collection receptacle is a tube or bag (Col. 6 & 19, 8-10 & 57-58, respectively).

Re claim 11, Soller discloses an analytical apparatus for analyzing blood wherein the calibration equation is determined in advance using the near infrared apparatus in relation to a plurality of blood specimens with different, known object characteristics (Col. 10, 18-38).

Re claim 12, Soller discloses a sample being collected into test tubes (Col. 1, 18-21) of the recited type (Col. 5, 53-64).

Re claim 13, Soller discloses an analytical apparatus for analyzing blood wherein the light conduction means comprises an optical fiber bundle (Col. 12, 59-62).

Re claim 14, Soller discloses a method wherein the sample is collected into test tubes (Col. 1, 18-21) of the recited type (Col. 5, 53-64).

Re claim 17, Soller discloses a method for analyzing a blood sample using NIR (Col. 3, 6-13).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soller et al. and Wright et al. in view of Brown et al. (US 4,134,678) and Alfano et al. (US 6,006,001).

Re claim 7, Soller discloses the claimed invention according to claim 5 but fails to disclose a monochromatic near infrared light source and a silicon detector. However, it is obvious and well known in the art of spectroscopy to use silicon detectors with a monochromatic light source during spectroscopic analysis as suggested by Alfano (Col. 2, 25-41). It is the position of the Office that even though Soller does not disclose the use of a monochromatic light source in conjunction with a silicon detector directly, it is inherent in the art of spectroscopic analysis of a sample to use a silicon detector or equivalent when undertaking spectroscopic analysis of a sample with a monochromatic light source. In light of the applicant's disclosure, there is no critically distinguishing light source or detector feature in the applicant's disclosure that exemplifies novelty over prior art disclosure. Therefore, it is understood that the reference of Soller reads on applicants' claimed limitation.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soller et al. and Wright et al. in view of Brown et al. and Ikeda et al. (US 4,936,674).

Re claims 18 and 19, Soller teaches the claimed invention but fails to show wherein an optical path length for said blood sample receptacle is 1-2 cm. Ikeda shows that it is known to

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provide an optical path length for a blood sample receptacle is 1-2 cm (col. 6, lines 37-58) for an apparatus for determining functions of blood cells. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the apparatus of Soller in view of Benz and Brown with the optical path length of Ikeda for the purposes of providing a suitable means for the measurement of fine variations in platelets in blood cells (Col. 4, 12-15).

Response to Arguments

Applicant's arguments filed 9/7/05 have been fully considered but they are not persuasive. Applicant's arguments regarding claims 1, 4, 5, 10-12, and 14 state that Soller fails to suggest using test tubes having substantially the same optical specifications. Soller discloses in column 20, lines 7-17 that the same type of sample holder was used through the entire experiment where in column 19, lines 57-58 a set of 10 measurements were taken using capillary tubes. It is well known in the art that cuvettes and tubes are art recognized equivalents. Furthermore, the term "ordinary" is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree. Applicant's argument's regarding claim 16 and 17 state that Soller fails to suggest analyzing an unmodified field sample. Soller's invention teaches a method of determining hematocrit in blood samples and does not teach modifying the sample prior to or after measurement. Therefore, it is determined that the sample being analyzed by Soller is an unmodified field sample. Applicant's argument regarding the wavelength of infrared light used is overcome by Soller in column 11, lines 51-55 wherein Soller discloses using infrared light having a wavelength of 700nm – 1100nm. In response to applicant's argument that Wright is nonanalogous art, it has been held that a prior art reference

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must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Wright discloses a method of NIR analysis wherein said method comprises the use of a ceramic tile as a reference material for calibration. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcus H. Taningco whose telephone number is (571) 272-1848. The examiner can normally be reached on M - F 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Porta can be reached on (571) 272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MT


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